The Joint Commission will be implementing the new Medication Compounding Certification (MDC) program for hospitals, critical access hospitals, and home care pharmacy organizations in the state of Michigan on 1/9/17. This Certification will assess organizations' compliance with Joint Commission standards based on the USP Chapter <797> requirements on sterile compounding. The Joint Commission has received a number of questions about the standards in this new program and this FAQ document was developed to address them:

Number	Question	Answer	Comment
1	What is the definition of compounding?	The MDC Certification glossary contains a definition of compounding. The glossary, along with other helpful MDC documents, can be found at this link: https://www.jointcommission.org/certification/medication_compounding.aspx	
2	How can I access the MDC Certification standards?	The standards are available on our website. https://www.jointcommission.org/certification/medication_compounding.aspx	
3	Is it sufficient to use an SOP and attach it to the management operating directive (a type of policy specific to the organization) to use as a policy?	No.	
4	In the proposed update to USP Chapter <797>, the requirement for garbing is cleanest to dirtiest. The current USP Chapter <797> requirements for garbing is dirtiest to cleanest. Which will you be looking for to be in compliance?	The proposed USP Chapter <797> changes have	

6	Does the buffer room have to be ISO Class 7? If it is ISO Class 5, is it okay if you re-alcohol?	Based on the guidance in USP Chapter <797>, the buffer room must be ISO Class 7 or better. If the buffer room is ISO Class 5, once items are entered into the direct compounding area, staff must re-alcohol these items (USP Chapter <797>, suggested SOPs 17, 18, 19).	
7	In the organization, the ER has a compounding area (unclassified) with an ISO Class 5 laminar flow hood. What is considered a good segregated compounding area? Does this room need to be a physically separated area, or is a room with an area demarcated acceptable?	Joint Commission engineers do not answer specific pharmacy infrastructure and design questions (or review infrastructure designs) prior to construction. The organization should refer to USP Chapter <797> requirements when planning for construction or changes to their compounding pharmacy. Any hospital or home care organization engaging with a consultant and/or contractor to construct these types of areas should consider whether or not the person engaged and overseeing the process has working knowledge of USP requirements. Another resource that may be of help are the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014, at Sections 2.1-4.2 entitles “Pharmacy Services”.	
8	The new expanded list of hazardous medications contains many which are compounded for immediate use. Will reviewers only be looking at antineoplastics or will they look at other hazardous drugs for immediate use?	Reviewers will very likely look at antineoplastics, but they may also look at other hazardous medications that are being compounded. See the new NIOSH list of hazardous medications: https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf	
9	Several standards about the physical environment (such as MDCSN.3, MDCN.3, MDCS.1) often refer to USP Chapter <797>. With the pending changes that will occur with USP Chapter <800>, is there an engineering matrix or flow chart	The USP Chapter <800> requirements do not go into effect until July 1, 2018. The surveyors will be surveying to the MDC Certification standards, which are based on the current USP Chapter <797> requirements.	

	for everything including ACPH, pressure relationships, temperature and humidity, and monitoring of these?		
10	If we are going to do		

14	Do you have a schematic outlining pressure differentials for USP Chapter <797> vs USP Chapter <800>?	No, we do not have this. Please refer to USP Chapter <797>; USP Chapter <800> is not yet in effect, so you will not be reviewed to USP Chapter <800>.

	and have several construction questions concerning materials used for the walls, counter tops, flooring, paint, lighting, and doors. We also have questions about the number and type of required air exchanges in the buffer room and clean room.	requirements for these items, and work with your engineers to ensure that the work is done properly. For example, the countertops need to be installed in a manner that prevents the risk of bacterial or infectious process proliferation, and they must be able to withstand the rigorous cleaning required. Joint Commission engineers do not review clean room design plans (or any other infrastructure designs) prior to construction. Any hospital engaging with a consultant and/or contractor to construct the area should consider whether or not the person engaged and overseeing the process has working knowledge of USP Chapter <797> requirements. Another resource that may be of help are the Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014, at Sections 2.1-4.2 entitled "Pharmacy Services".	
19	What products are acceptable to be used to wipe down items brought into the clean side of the anteroom? Also, what products can be used to wipe down the clean room hoods and chemo hoods?	The Joint Commission does not provide guidance regarding specific products that are acceptable for proper cleaning. The organization needs to investigate various products to determine which meet the USP Chapter <797> requirements and the needs of the organization.	
20	Unlike most pharmacies, our pharmacists do the compounding. Our pharmacy technicians are only responsible for attaching the vial using the MINI-BAG Plus System and the VIAL-MATE Adaptor Device. Are the technicians required to do Media fill and gloved fingertip testing? Can this function be done	The coupling of MINI-BAG Plus and VIAL-MATE are not considered compounding per USP Chapter <797> and therefore these pharmacy technicians would not be required to complete the training elements required for a compounding employee if they are not compounding. Caution should be made to ensure that these items are being coupled in the ISO Class area required by the manufacturer. If this does involve utilization of the ISO Class 5 or Class 7 buffer areas, then it would be prudent to ensure they have training on that environment and appropriate restrictions to ensure the integrity of that area.	

The Joint Commission
Medication Compounding Certification (MDC) – FAQs

23	With USP Chapter <800>, the oncology meds need to be stored in the negative pressure room. It was mentioned in the overview that the chemo vials have to be removed from the non-corrugated cardboard boxes before going into the room. We would like to confirm this. We do see some problems if we need to return the medications to the wholesaler. With the cost of these medications, we do send medications back if a patient's treatment changes and won't be needed the product.	USP Chapter <800> does not go into effect until July 2018. Guidance regarding USP Chapter <800> cannot be provided at this time. Organizations will not be reviewed for compliance with USP Chapter <800>.	
24	Are the use of closed system transfer devices a current requirement when compounding hazardous drugs in a Class II Type A2 cabinet in a non-negative pressure room? Will there be a requirement for compounding in a negative pressure room?	Yes, closed system transfer devices are required when compounding hazardous drugs in a Class II Type A2 cabinet in a non-negative pressure room. If the organization does a low volume of compounding of hazardous medications it would be acceptable for the organization to use a CSTD in a non-negative pressure room based on USP Chapter <797>. Optimally, all hazardous medications should be compounded in a hood that is 100% vented to the outside.	
25	Can you explain the master formulary record requirement?	This requirement is for nonsterile compounding, and is based on USP Chapter <795> at: XI. Compounding Documentation. Because we are not reviewing nonsterile compounding for the MI organizations on the first reviews, it does not apply to the initial reviews. For your information, it is addressed at MDCN.07, EP5.	

26	At the MI training, someone mentioned that we need to have a signed Hazardous Drug Risk Acknowledgement for	

room air quality is consistently maintaining an ISO Class 7 environment. We are also in the process of building a new facility, so I need to determine how much renovation needs to occur in our existing facility which we are expected to vacate in 2018.

ne[typef bui exa)-4(s shouldjat9-ideriche)Tr or note